UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,956	07/25/2007	Yoshihiko Abe	1029650-000176	8661

21839 7590 12/10/2008

BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
HEINCER, LIAM J	

ART UNIT	PAPER NUMBER
1796	

NOTIFICATION DATE	DELIVERY MODE
12/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/592,956	ABE ET AL.	
	Examiner	Art Unit	
	Liam J. Heincer	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: hyaluroinc acid is listed as both a polysaccharide containing carboxyl groups naturally, and as a polysaccharide not containing a carboxyl group naturally in the original specification (¶0046 and 0051).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Considering Claims 33 and 34: Instant claim 33 requires the pH adjuster to be in "non-mixed state with the cross-linking polysaccharide derivative". It is not clear how the pH adjuster is present in the composition without mixing, and if it was, how it could influence the adhesion preventive material. In the claimed method the adhesion preventive material is provided prior to application to the biological site (Claim 21). However, in the original specification it appears that “non-mixed state” indicates that the pH adjuster is mixed with the saccharide at the biological site (¶0074-77). For the purpose of further examination, the claim is being interpreted as requiring the pH adjuster to be mixed at the biological site.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-29, 31, 32, and 35-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Aeschilmann et al. (US Pat. 6,630,457).

Considering Claims 21, 24, 25, and 36: Aeschilmann et al. teaches a method comprising providing composition comprising a crosslinkable (16:8-11) activated ester of hyaluronic acid and hydroxysuccinimide (16:20-33) and crosslinking the activated hyaluronic acid in the presence of tissue surfaces/biological sites (18:45-49) where the activated hyaluronic acid reacties with a active hydrogen to crosslink (16:8-17:21). Aeschlimann et al. also teaches crosslinking the activated ester in water under alkaline conditions (Example 9).

Considering Claim 22: Aeschilmann et al. teaches reacting the hyaluronic acid compounds as reacting with other hyaluronic acid compounds/self crosslinking (17:60-66).

Considering Claim 23 and 35: Aeschilmann et al. teaches the activated hyaluronic acid as reacting cocurrently with the tissue surface/biological surface (18:45-49).

Considering Claims 26 and 37: Aeschilmann et al. teaches the substitution of activating group as being greater than 0.2 mmoles/g, with 0.6 mmoles/g being optimal (16:65-17:4).

Considering Claim 27 and 38: Aeschlimann et al. teaches the polysaccharide as being hyaluronic acid/a polysaccharide having carboxy groups (16:8-11). Since their would not be 100% yield in the process and polysaccharide already contains carboxy groups, the derivative would also contain carboxy groups.

Considering Claim 28 and 39: Aeschilmann et al. does not teach using a salt derivative of the hyaluronic acid.

Considering Claim 29: Aeschlimann et al. teaches one the polysaccharides disclosed in the original specification. Therefore it is assumed that the polysaccharides would have the same solubility in solvent.

Considering Claim 31: Aeschilmann et al. teaches the pH during curing as being 7.4 - 8.5 (Example 9).

Considering Claim 32: Aeschilmann et al. teaches an amine functional hyaluronic acid/a polymer other than the cross-linking polysaccharide derivative (17:60-66).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aeschilmann et al. (US Pat. 6,630,457) as applied to claim 21 above, and further in view of Barbucci et al. (WO 00/27886).

Considering Claim 30: Aeschilmann et al. teaches the method of claim 21 as shown above.

Aeschilmann et al. does not teach the polysaccharide as being one in which the raw material does not contain a carboxyl group. However, Barbucci et al. teaches using carboxymethyldextran, carboxymethylcellulose, or carboxymethylstarch as a

crosslinkable polysaccharide with activated ester groups (4:24-5:3). Aeschilmann et al. and Barbucci et al. are analogous art as they are concerned with the same field of endeavor, namely polysacchrides with activated ester groups for use in anti-adhesion gels. It would have been obvious to a person having ordinary skill in the art at the time of invention to have used the polysaccharides of Barbucci et al. in the method of Aeschilmann et al., and the motivation to do so would have been, as Barbucci et al. suggests, they are functionally equivalent to hyaluronic acid (4:24-5:3).

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aeschilmann et al. (US Pat. 6,630,457) as applied to claim 21 above.
Considering Claim 33: Aeschilmann et al. teaches the method of claim 21 as shown above. Aeschilmann et al. also teaches adding a pH adjuster to the hydrogel forming composition (Example 9).

Aeschilmann et al. does not teach adding the pH adjuster at the biological site. However, the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. See MPEP § 2144.04. It would have been obvious to a person having ordinary skill in the art at the time of invention to have added the pH adjuster after application to the tissue, and the motivation to do so would have been, as Aeschilmann et al. suggests, the crosslinking reaction will only occur in alkaline conditions (16:25-30), so addition of the pH adjuster in situ will prevent premature crosslinking.
Considering Claim 34: Aeschilmann et al. teaches an amine functional hyaluronic acid/a polymer other than the cross-linking polysaccharide derivative (17:60-66).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21, 24, 25, and 32-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 12/178,030. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 26 of application '030 teaches applying a polysaccharide derivative with active ester groups introduced in the side chain to a living organism/biological site and reacting the material in the presence of water under alkaline conditions. Although the claim does not explicitly teach forming a crosslinked material, this would inherently occur during the reaction under alkaline conditions. Claims 27 and 28 teach adding a pH adjusting agent and additional polymer respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed September 3, 2008 have been fully considered but they are not persuasive.

Applicants argument that Aeschilmann et al. does not teach applying the polysaccharide to a biological site is not persuasive. Aeschilmann et al. does in fact teach applying the polysaccharide to tissue to prevent adhesion (18:45-19:18).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/ LJH

Supervisory Patent Examiner, Art Unit 1796 November 24, 2008